

REMARKS

The Amendments

The amendments to the specification are made in view of some recently noticed minor informalities.

The indication in Examples 2 and 3 of which Figures show data on the tablet cores and which show data on film-coated tablets is corrected. The Figures were correctly identified in the Brief Description / I the Drawings at page 3 and the change is supported thereby.

Examples 2, 3 and 5 have been changed to the present tense because it was recently discovered that the tablets actually tested in the part of Example 2 which provides the data in Figure 1 and in Example 5 were not exactly the same as described in Example 1. The starch contained in the tablets tested for Example 2, Figure 1, and in Example 5 was all (i.e., 24 mg) corn starch, rather than a mix of corn starch and modified starch totaling 24 mg (i.e., 14.4 mg corn starch and 9.6 mg modified starch). Further, the amount of lactose monohydrate in those tablets was 48.57 mg in the 3 mg tablet and 49.57 mg in the 2 mg tablet rather than 48.17 mg, the amount of magnesium stearate was 0.4 mg rather than 0.8, the Macrogol 4000 rather than 6000 was used, and no ferric oxide pigment was used in the coating solution of the coated tablets. This tense change is believed to raise no issue of prior art. The change is needed to ensure compliance with MPEP 608.01(p)(II) since these examples, as written, are prophetic in nature, involving predicted test results.

The claim amendments do not require any new search. Claims 7, 45, 47, 49 and 58 are amended to correct an obvious typographical error made evident by the 35 U.S.C. §112 rejection in the Office Action mailed March 23, 2004. Support for the correction is found in Example 2, page 12, line 11, of the specification. Claim 58 is also amended to correct another obvious typographical

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error. The further claim amendments are merely of a technical nature in order to avoid possible formalistic issues under 35 U.S.C. §102(f), as explained below.

Change of Inventorship

The change the inventorship filed concurrently changes the inventorship of this application from

Heil, Heithecker, Hilman & Lipp

to

Heil, Heithecker, Hilman, Lipp, Hueimpel & Tack.

In the mid to later 1980s, the two added inventors developed micronized drospirenone, in amounts within the claimed ranges, for the intended purposes of female fertility control using the predominant mode of oral contraception, i.e., 21 days of estrogen and progestin followed by 7 active ingredient free days (termed "21/7 day regimen" below). In the mid to later '90s, the originally named four inventors independently took up this earlier development and, as a result, these four caused the above-identified patent application to be drafted. As filed, it included claims to the inventions of both the earlier 2-man inventive entity (including kits for the 21/7 day regimen) and the 6-man inventive entity (kits for oral contraception regimens different from the 21/7 day regimen). *Sandra Solomon v. Kimberly-Clark Corporation*, 216 F.3d 1372, 55 USPQ2d 1279 (Fed. Cir. 2000); *Kimberly-Clark Corporation v. Proctor & Gamble Distributing*, 973 F.3d 911, 23 USPQ2d 1921 (Fed. Cir. 1992).

When the claims were originally drafted, it was not realized that two inventive entities were involved. As a result, certain individual claims encompassed subject matter of both inventive

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entities, i.e., kits drawn to both the 21/7 day regimen and to other regimens. Thus, these claims would have a 6-man inventive entity overall. This could raise the issue of whether such a claim was technically anticipated by the earlier 2-man invention. Accordingly, the technical amendments made here eliminate the previous coverage by kit claims 10, 11, 16, 46 and 47 of subject matter which was invented by the 6-person inventive entity. These claims now cover only the 21/7 day regimen kits ("at least 21" replaced by "21"). Claims 12 and 13, previously dependent on claims 11 and 10, respectively, must be made independent since they are now drawn only to regimens other than the 21/7 day regimen. Clearly, no burden is placed on the Examiner by these changes because the claims still cover only what was previously fully examined.

In this fashion, none of the claims raises any issue of anticipation under 35 U.S.C. §102(f). To the extent there might have been or are any potential issues under 35 U.S.C. §103 / 35 U.S.C. §102(f), these have always been moot under 35 U.S.C. §103(c) since all inventions claimed in this application at all times were commonly owned by the sole assignee, Schering AG.

The inventorships of the claims of this application (as amended here) have been determined to be as follows:

Huempel & Tack:

Claims 1, 3-7, 9-11, 16, 17, 36-39, 41, 43-47, 66-68, and to the extent they depend from any of the foregoing claims, also claims 50-56 and 60-65.

Heil, Heithecker, Hilman, Lipp, Huempel & Tack:

Claims 12-14, 18, 19, 21, 22, 40, 42, 48, 49, 57-59, 69, and to the extent they depend from any of the foregoing claims, also claims 50-56 and 60-65.

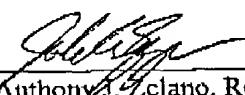
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The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted.


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Attorney Docket No.: PLOVIN-1A

Date: March 29, 2004

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